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Date: September 28, 2001 By: [Signature]

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF.

Yasufumi Kaneda

EXAMINER: unknown

SERIAL NO.: Not yet Assigned

ART UNIT: unknown

FILED: Concurrently Herewith

FOR: **VIRUS ENVELOPE VECTOR FOR GENE
TRANSFER**

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination and calculation of the filing fee of the above-referenced application, please amend the application as follows.

In the specification: On page 1, before the paragraph starting on line 5, insert the following paragraph:

This application claims priority to application no. PCT/JP01/00782 filed 02 February 2001, now publication no. WO 01/57204 published 09 August 2001; which claims priority to JP 25596 filed 02 February 2000, which are both incorporated herein by reference.

In the Claims: Please amend claims 3, 5-7, 10-14, 16-19 and add new claims 20-36 as follows:

3. (Amended) A gene transfer vector according to claim 1, wherein the virus is derived from a virus belonging to a family selected from the group consisting of Retroviridae, Togaviridae, Comoviridae, Flaviviridae, Paramyxoviridae, Orthomyxoviridae, Bunyaviridae, Rhabdoviridae,

Poxviridae, Herpesviridae, Baculoviridae, and Hepadnaviridae.

5. (Amended) A gene transfer vector according to claim 1, wherein the gene transfer vector is prepared by a method which comprises the steps of:
- mixing the virus with an exogenous gene; and
 - freezing and thawing the mixture two or more times.
6. (Amended) A gene transfer vector according to claim 1, wherein the vector is prepared by a method which comprises a step of mixing the virus with an exogenous gene in the presence of a detergent.
7. (Amended) A gene transfer vector according to claim 5, wherein the method further comprises a step of inactivating the virus.
10. (Amended) A gene transfer vector according to claim 5, wherein the method further comprises a step of adding protamine sulfate to the exogenous gene.
11. (Amended) A gene transfer vector according to claim 1 for introducing a gene into animal in vivo tissue.
12. (Amended) A gene transfer vector according to claim 11, wherein the tissue is selected from the group consisting of the liver, skeletal muscles, the uterus, brain, eyes, carotid arteries, skin, blood vessels, the lung, the heart, kidneys, the spleen, cancer tissue, nerves, B lymphocytes, and respiratory tract tissue.
13. (Amended) A pharmaceutical composition for gene therapy which comprises a gene transfer vector containing a virus envelope.
14. (Amended) A kit for screening gene libraries, which comprises a gene transfer vector containing a virus envelope.

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16. (Amended) A method for preparing a gene transfer vector comprising a virus envelope for gene transfer, wherein the method comprises the step of:
mixing the virus with an exogenous gene in the presence of a detergent.
 17. (Amended) The method according to claim 15, further comprising the step of inactivating the virus.
 18. (Amended) A method for introducing a gene into isolated animal tissue, wherein the method comprises the steps of:
preparing a gene transfer vector containing a virus envelope and a desired exogenous gene; and
introducing a gene into the isolated animal tissue via the gene transfer vector.
 19. (Amended) A method for introducing an exogenous gene into a suspended cell, wherein the method comprises the steps of:
mixing the suspended cell with a gene transfer vector containing a virus envelope in the presence of protamine sulfate; and
centrifuging the mixture.
 20. (New) A gene transfer vector according to claim 6, wherein the method further comprises a step of inactivating the virus.
 21. (New) A gene transfer vector according to claim 20, wherein the detergent is selected from the group consisting of octylglucoside, Triton-X100, CHAPS and NP-40.
 22. (New) The gene transfer vector according to claim 21, wherein the detergent is octylglucoside.
 23. (New) The gene transfer vector according to claim 6, wherein the method further comprises a step of adding protamine sulfate to the exogenous gene
 24. (New) The pharmaceutical composition according to claim 13, wherein the virus is derived from a wild-type or a recombinant-type virus.

25. (New) The pharmaceutical composition according to claim 13, wherein the virus is derived from a virus belonging to a family selected from the group consisting of Retroviridae, Togaviridae, Cornoviridae, Flaviviridae, Paramyxoviridae, Orthomyxoviridae, Bunyaviridae, Rhabdoviridae, Poxviridae, Herpesviridae, Baculoviridae, and Hepadnaviridae.
26. (New) The pharmaceutical composition according to claim 13, wherein the virus is HIV.
27. (New) The kit according to claim 14, wherein the virus is derived from a wild-type or a recombinant-type virus.
28. (New) The kit according to claim 14, wherein the virus is derived from a virus belonging to a family selected from the group consisting of Retroviridae, Togaviridae, Cornoviridae, Flaviviridae, Paramyxoviridae, Orthomyxoviridae, Bunyaviridae, Rhabdoviridae, Poxviridae, Herpesviridae, Baculoviridae, and Hepadnaviridae.
29. (New) The kit according to claim 14, wherein the virus is HIV.
30. (New) The method according to claim 16, further comprising the step of inactivating the virus.
31. (New) The method according to claim 18, wherein said virus is derived from a wild-type or a recombinant-type virus.
32. (New) The method according to claim 18, wherein the virus is derived from a virus belonging to a family selected from the group consisting of Retroviridae, Togaviridae, Cornoviridae, Flaviviridae, Paramyxoviridae, Orthomyxoviridae, Bunyaviridae, Rhabdoviridae, Poxviridae, Herpesviridae, Baculoviridae, and Hepadnaviridae.
33. (New) The method according to claim 18, wherein the virus is HIV.
34. (New) The method according to claim 19, wherein the virus is derived from a wild-type or a recombinant-type virus.

35. (New) The method according to claim 19, wherein the virus is derived from a virus belonging to a family selected from the group consisting of Retroviridae, Togaviridae, Coronaviridae, Flaviviridae, Paramyxoviridae, Orthomyxoviridae, Bunyaviridae, Rhabdoviridae, Poxviridae, Herpesviridae, Baculoviridae, and Hepadnaviridae.

36. (New) The method according to claim 19, wherein the virus is HIV.

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REMARKS

The specification has been amended to add the priority information. The claims have been amended to remove multiple dependencies. New claims 20-36 find support in the original claims as filed. Accordingly, no new matter has been added. Entry of the amendments prior to examination is respectfully requested.

The Examiner is invited to contact Applicants' representative at 650-838-4410 if prosecution of this application would be assisted thereby.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

This application claims priority to application no. PCT/JP01/00782 filed 02 February 2001, now publication no. WO 01/57204 published 09 August 2001; which claims priority to JP 25596 filed 02 February 2000, which are both incorporated herein by reference.

In the claims:

3. (Amended) A gene transfer vector according to claim 1 [or 2], wherein the virus is derived from a virus belonging to a family selected from the group consisting of [.] Retroviridae, Togaviridae, Cornoviridae, Flaviviridae, Paramyxoviridae, Orthomyxoviridae, Bunyaviridae, Rhabdoviridae, Poxviridae, Herpesviridae, Baculoviridae, and Hepadnaviridae.
5. (Amended) A gene transfer vector according to [any one of] claim[s] 1 [to 4], wherein the gene transfer vector is prepared by a method which comprises the steps of:
mixing the virus with an exogenous gene; and
freezing and thawing the mixture two or more times.
6. (Amended) A gene transfer vector according to [any one of] claim[s] 1 [to 4], wherein the vector is prepared by a method which comprises a step of mixing the virus with an exogenous gene in the presence of a detergent.
7. (Amended) A gene transfer vector according to claim 5 [or 6], wherein the method further comprises a step of inactivating the virus.
10. (Amended) A gene transfer vector according to [any one of] claim[s] 1 to 9] 5, wherein the method further comprises a step of adding protamine sulfate to the exogenous gene.

11. (Amended) A gene transfer vector according to [any one of] claim[s] 1 [to 10] for introducing a gene into animal in vivo tissue.
12. (Amended) A gene transfer vector according to claim 11, wherein the tissue is selected from the group consisting of[.] the liver, skeletal muscles, the uterus, brain, eyes, carotid arteries, skin, blood vessels, the lung, the heart, kidneys, the spleen, cancer tissue, nerves, B lymphocytes, and respiratory tract tissue.
13. (Amended) A pharmaceutical composition for gene therapy which comprises [the] a gene transfer vector [according to claims 1 to 12] containing a virus envelope.
14. (Amended) A kit for screening gene libraries, which comprises [the] a gene transfer vector [according to claims 1 to 12] containing a virus envelope.
16. (Amended) A method for preparing a gene transfer vector comprising a virus envelope for gene transfer, wherein the method comprises the step[s] of:
mixing the virus with an exogenous gene in the presence of a detergent.
17. (Amended) [A] The method according to claim 15 [or 16], further comprising the step[s] of inactivating the virus.
18. (Amended) A method for introducing a gene into isolated animal tissue, wherein the method comprises the steps of:
preparing a gene transfer vector [according to any one of claims 1 to 12, containing] containing a virus envelope and a desired exogenous gene; and
introducing a gene into the isolated animal tissue via the gene transfer vector.
19. (Amended) A method for introducing an exogenous gene into a suspended cell, wherein the method comprises the steps of:
mixing the suspended cell with [the] a gene transfer vector [according] containing a virus envelope [to any one of claims 1 to 12] in the presence of protamine sulfate; and
centrifuging the mixture.